Guidance for Industry

# Over the Counter (OTC) Screening Tests for Drugs of Abuse: Guidance for Premarket Notifications

## *Draft Guidance - Not for Implementation*

This guidance document supersedes the Draft Guidance for Premarket Submissions for Tests for Screening Drugs of Abuse to Be Used By The Consumer, December 30, 1998

**This guidance document is being distributed for comment purposes only.**
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**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Center for Devices and Radiological Health**

**Clinical Chemistry and Toxicology Branch**
**Division of Clinical Laboratory Devices**
**Office of Device Evaluation**

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# Preface

## Public Comment:

For 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this document should be submitted to the Docket No. assigned to that notice, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852.

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# Over the Counter (OTC) Screening Tests for Drugs of Abuse: Guidance for Premarket Submissions

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## INTRODUCTION:

This document addresses drugs of abuse **urine screening tests** where the initial screening tests are performed and interpreted by the OTC user and screened presumptive positive results are mailed to certified laboratories for further testing. Essential analytical characteristics for these screening devices are discussed in FDA guidance, Review Criteria for Assessment of In Vitro Diagnostic Devices for Drugs of Abuse Assays Using Various Methodologies on the web at http://www.fda.gov/cdrh/ode/odecl052.html.

As part of its efforts to ensure that FDA considers the least burdensome path to market, the agency has drafted this guidance to

- Clarify that OTC screening tests for drugs of abuse ordinarily will be reviewed as a premarket notification
- Suggest the use of spiked urine samples instead of urine obtained from individuals using drugs
- Suggest combining drugs in these spiked urine samples in order to reduce the number of samples tested

This document describes the additional consumer studies and labeling considerations applicable to OTC screening devices. While the basic study designs described in this guidance are applicable to other matrices, **testing of body fluids or sample types other than urine may introduce additional issues beyond the scope of this document.**

Premarket review of any *in vitro* diagnostic (IVD) test where testing is performed in an

OTC setting requires consideration of two key issues:

1. Can the OTC user perform the test and obtain acceptable initial screening results?
2. Can the product be labeled in a manner to assure that use of the test in an OTC setting provides information that can be used by the tester?

**OTC Settings** - FDA believes that there should be consistency in its regulation of drugs of abuse screening tests used in the home, workplace, insurance, and sports settings. Concerns related to OTC use are similar in all of these settings, including concerns about sample integrity and test accuracy. FDA intends to apply this guidance document to OTC tests for drugs of abuse in these non-professional use settings: home, workplace, insurance, and sports. FDA would continue to defer oversight for forensics (law enforcement) applications to the existing system of legal controls.

## PURPOSE:

This document is intended to be used in conjunction with the Code of Federal Regulations (21 CFR 807) and to FDA Publication Number 97-4224, the manual entitled *In Vitro* Diagnostic Devices: Guidance For The Preparation of 510(k) Submissions on the web at http://www.fda.gov/cdrh/manual/ivdmanul.html. It is intended to provide additional guidance and clarification for this type of device.

## DESCRIPTION OF DEVICE:

This type of device is one intended for use in an OTC setting as an IVD screening test for any single one, or combination of, the following five substances in urine:

Amphetamine or methamphetamine
Cocaine
Cannabinoids
Opiates
Phencyclidine

Although barbiturates, benzodiazepines, ethanol, inhalants, and other drugs are widely abused, the focus of this document is on the above five drugs, because testing programs and procedures have been particularly well characterized.

The products addressed here are screening or initial testing devices. These devices are typically designed to be simple, rapid, and reasonably sensitive. The results provided by these devices indicate whether the drug or drug metabolite **may** be present. A positive result from a screening device is considered to be a **presumptive** result and **should never be interpreted as final without laboratory confirmation.**

A premarket notification [510(k)] for these IVD screening tests should include:

1) adequate directions for the OTC user to perform and properly interpret the drug screen in an OTC setting,

2) labeling that indicates a positive result is reported as **"uncertain," "preliminary," "inconclusive,"** or **"maybe",**

3) labeling that includes a recommendation for follow-up with a health care provider,

4) information that shows the cost of confirmation testing is included in the price of the product and access to confirmation testing in a certified laboratory setting is provided as part of the test,

5) information that shows that in the hands of the OTC user, a majority of results will be correct at concentrations 25% above and below the cutoff and essentially all results will be correct at concentrations 50% above and below the cutoff.

Manufacturers of OTC screening tests for drugs of abuse who do not assure access to confirmation testing should provide additional data/information to substantiate that the test is substantially equivalent to laboratory-based systems which maximize the likelihood that appropriate confirmation testing is performed. Tests that do not assure access to confirmation testing may be considered by an FDA Advisory Panel. This is because there will likely be new types of questions of safety and effectiveness for screening products without available confirmation testing. Earlier deliberations of an FDA Advisory Panel indicated that only those devices whose level of performance approaches that of gas chromatography/mass spectroscopy (GC/MS) are appropriate for OTC marketing without confirmation testing.

## ANALYTICAL PERFORMANCE CHARACTERISTICS:

The performance of a new device may be demonstrated by using a valid evaluation protocol. The National Committee for Clinical Laboratory Standardization (NCCLS) is a good source for evaluation methods. NCCLS, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, Tel (610) 688-0100, Fax (610) 688-0700, e-mail exoffice@nccls.org, or their home page at http://www.nccls.org.

The 510(k) should contain evidence that the device, when used in an OTC setting, is substantially equivalent to another device (the predicate device) that is legally marketed in the United States. This document does not address the information that should be submitted to demonstrate that the product meets analytical parameters. New OTC devices should have all analytical performance parameters characterized in a manner consistent with FDA guidance,

Review Criteria for Assessment of In Vitro Diagnostic Devices for Drugs of Abuse Assays Using Various Methodologies (on the web at http://www.fda.gov/cdrh/ode/odecl052.html). You should consult the latest version of that guidance document to ensure that appropriate studies have been completed. ***This guidance addresses only the additional studies recommended for OTC claims.*** If a device has previously been cleared for non-OTC use, the submission should include a summary of the analytical studies previously performed and a reference to the 510(k) number of the earlier submission to hasten the review process.

**A. OTC Accuracy and Precision**

1. **Overview**

   There should be a consumer field study to demonstrate that OTC users can correctly follow the labeling instructions, obtain acceptable initial test results, and interpret the meaning of these initial results. Therefore, FDA recommends that studies be conducted at three or more independent locations and include a statistically adequate number of consumers to represent the populations expected to use the test. Inclusion of a demographically diverse group that includes a range of ages, education, and regional variation will allow extrapolation of observations from the sampled group to the general public.

2. **Sample type and distribution**

   The number of consumers and samples in a study should be sufficient to demonstrate accuracy and precision in the hands of the OTC user. FDA recommends that for each drug, at least 200 samples are tested by 200 consumers (i.e., one sample per consumer) equally divided over the three sites. Since accuracy data is most meaningful when the concentrations of the samples analyzed are near the cutoff concentration, emphasis should be placed on samples with concentrations near the cutoff value. An appropriate sample distribution is as follows:

   20 samples for low negative concentrations

   30 samples at 50% below cutoff concentration

   50 samples at 25% below the cutoff concentration

   50 samples at 25% above the cutoff concentration

   30 samples at 50% above the cutoff concentration

   20 samples for high positive concentrations

   The study may use sample pools of human urine known to be drug-free (but not stripped) and spiked with known amounts of drug. The concentrations of drug or metabolite in each sample pool should be confirmed by GC/MS. Aliquots from each sample pool may then be used in the OTC study.

If several drugs are to be evaluated in the study, the number of samples can sometimes be reduced by having a portion of the samples contain a combination of two drugs. An example of an appropriate study design that uses samples containing combinations of drugs is shown below in Table 1. FDA believes that adequate study designs would incorporate the distribution of drug concentrations listed above, and for example, 30 samples containing no drug and 30 samples containing all drugs.

**Table 1 Suggested Sample Table for Use in Consumer Studies.** (Samples containing combinations of drugs, concentrations are shown as percent of the cutoff.)

| solution number | Drug A | Drug B | Drug C | Drug D | Drug E | Drug F | sample size |
|---|---|---|---|---|---|---|---|
| 1 | 125% | 125% | | | | | 50 |
| 2 | | 75% | 75% | | | | 50 |
| 3 | | | 125% | 125% | | | 50 |
| 4 | | | | 75% | 75% | | 50 |
| 5 | | | | | 125% | 125% | 50 |
| 6 | 75% | | | | | 75% | 50 |
| 7 | 50% | 150% | | | | | 30 |
| 8 | | 50% | 150% | | | | 30 |
| 9 | | | 50% | 150% | | | 30 |
| 10 | | | | 50% | 150% | | 30 |
| 11 | | | | | 50% | 150% | 30 |
| 12 | 150% | | | | | 50% | 30 |
| 13 | 200% | 200% | | | | | 20 |
| 14 | | | 200% | 200% | | | 20 |
| 15 | | | | | 200% | 200% | 20 |
| 16 | | | | | | | 30 |
| 17 | 150% | 150% | 150% | 150% | 150% | 150% | 30 |

### 3. Protocol for OTC tests

To evaluate the procedures associated with the product to be marketed, (e.g., mixing, timing, result interpretation), FDA recommends the following:

a) Provide the OTC user with the entire package insert draft.

b) Instructions and the instructional environment concerning how to perform or interpret the test should mimic those expected with the actual intended use of the device.

c) A study observer may monitor OTC studies, but should not provide assistance to the OTC user in performing or interpreting the test.

d) Testing of all specimens by the OTC users, as well as collation and recording of results, should be performed in a masked manner.

## B. OTC Surveys and Labeling Assessments

### 1. Reading level

To ensure that the typical OTC user is able to understand the labeling, it is important to evaluate the reading level of the material and demonstrate that it is no higher than the 7$^{th}$ grade level. The NCCLS document, "Labeling of Home Use In Vitro Testing Products: Approve Guideline: GP-14T," describes the SMOG test, an example of one method that can be used to evaluate the level of the reading material.

### 2. Evaluating whether the OTC user understands the results

One objective of the OTC study is to determine whether OTC users understand what the results mean, including the importance of confirmation testing. Therefore, FDA recommends that OTC users complete questionnaires after they have performed the test and recorded their results. Manufacturers should provide an opportunity for users to convey if they found certain parts of the package insert confusing. For this purpose, manufacturers may wish to list each section separately and give the users an opportunity to rate each on a scale of 1 to 5.

In addition, questions such as, "What is the next step to take if there is no line in the test window?", "What does it mean if you see a very light line in the test window?", or "Can foods or prescription drugs affect the results of the test?" may be used to assess OTC users' understanding of confirmation testing. Such questions are preferable to Yes/No questions (such as "Do you understand the meaning of the test results?") because Yes/No questions may not adequately assess user comprehension.

## C. Reporting of results and protocol in the 510(k)

### 1. Precision and accuracy data

Results of the OTC accuracy and precision studies should be clearly summarized in the 510(k). This can be accomplished by presenting a table of results for each drug. The data in each table should include:

a) the number of samples at each targeted concentration

b) the GC/MS values of each specimen pool

c) the number of positive and negative results generated from each pool

d) the percentage of correct results generated at each concentration

Data from the three sites may be pooled if there is no significant difference between sites. It is recommended that line data from the studies be kept on file, since they are sometimes helpful in evaluating the data.

### 2. Protocol summary

Items in the protocol summary should include:

(a) a summary of how the OTC study samples were prepared, including a description of the matrix material and the exact drug compound in the matrix

(b) a demographic description and breakdown of the OTC users in the study (including age, education, gender, and site) to indicate whether the participants were representative of the target population

(c) a summary of the verbal instructions given to the OTC users

(d) a description of how the samples were randomized and masked

(e) identification of any collators or surveyors

(f) a description of the sites where the studies were conducted

### 3. Results of questionnaire and labeling assessments

Results of the questionnaire may be presented in a summary format for all questions by indicating the number of respondents that gave each type of response. The tool used to determine the reading level of the labeling, as well as any score generated by the method, should be identified.

4. **Stability studies**

   The 510(k) should include the results of stability studies used to establish the expiration dating of the product. These results may be presented in summary format. Include information on:

   - the material being tested
   - the concentration of the drug levels in relation to the cutoff concentration
   - testing frequency, temperature and humidity conditions
   - acceptance criteria for the study

5. **Description of internal quality control checks and/or adulteration checks**

   The format of the OTC screening device may include "built-in" internal or reference control checks. These should be clearly described and should indicate what analytical components of testing (e.g., reagent uptake, reactivity of reagents) are addressed by the control checks. Manufacturers may also want to design drugs of abuse screening tests to identify possible sample adulteration (e.g., by monitoring pH or specific gravity). If adulteration checks are included in the device, they should also be described in the submission.

6. **Description of certified laboratory**

   The 510(k) should include a statement that a certified laboratory will be conducting confirmation testing and should specify the credentials of the laboratory.

7. **Summary of reporting format**

   The 510(k) should also describe how confirmed results will be reported to the consumer. Instructions on how to obtain professional counseling or medical assistance should be offered to any customer who received positive results and should be available upon request for negative results.

## LABELING

### A. Overview

The information in the labeling should be suitable for OTC users, sequenced in a way logical to OTC users, and conform to sections of 21 CFR 809.10 appropriate for OTC use. Instructions for use by OTC users should be directed at a reading comprehension level no higher than the 7$^{th}$ grade. Several publications may be used as references for

writing consumer labeling. The FDA publication, FDA 93-4258, Write it Right, available on the web at http://www.fda.gov/cdrh/dsma/897.pdf or from the Division of Small Manufacturers Assistance (DSMA) at 800-899-0381 and the NCCLS publication, Labeling of Home-Use In Vitro Testing Products, GP14-A, are sources for clear and concise instructions. Both manual methods and software programs are available to predict readability. Methods for enhancing the understanding of the text, e.g., consistent terms, active verbs, personal pronouns, OTC language, examples to explain concepts, may be found in the publications cited above. In addition, it may be very helpful for manufacturers to obtain labeling of previously cleared OTC drug of abuse screening tests to use as a guide.

Performance characteristics should not be included in the labeling unless additional intended use studies have been performed to characterize clinical sensitivity and specificity in an OTC environment. You should confer with DCLD to pursue this route. The labeling should emphasize the need for confirmation testing of presumptive positive results. In addition, manufacturers may consider use of additional methods to encourage confirmation testing by using options such as masking of individual analytes within a test.

**An OTC Package Insert should include the following elements:**

1. **Name of the device**

   In addition to the name of the device, a note, (in bold or capital letters) informing the consumer that it is very important to read all instructions before performing the test should be included.

2. **Intended use statement**

   Essential information about the product should be described, including a clear statement that the device is for OTC drugs of abuse screening and that urine is the type of sample being tested. A list of which drugs the screening test detects (including street names) can also be included in this section. It may be helpful to use a question and answer format (e.g., "What is the ABC Drug Screen Test?").

3. **Limitations of screening**

   In addition to reporting positive results as **"uncertain," "preliminary," "inconclusive,"** or **"maybe,"** a statement of the limitations of screening, in bold, under WARNING AND PRECAUTION should be included at the beginning of the package insert, immediately following the intended use statement. An example of a limitation statement is:

   ***(This device) is only the first step in a two step process to look for the presence of drugs of abuse. If your result is "uncertain," you must send the rest of the***

***urine sample to the laboratory to find out whether there are drugs in the sample. The laboratory test is more accurate than the home test and there is no extra cost for the laboratory test.***

**4. Contents of the screening test**

A list and description of all contents, including materials necessary for confirmation testing should be provided. FDA encourages the use of illustrations. The package insert should advise OTC users to check for, or familiarize themselves with the materials and provide a telephone number to call in case of missing contents.

**5. Storage conditions**

The package insert should indicate appropriate storage conditions for the test and advise OTC users to note the expiration date.

**6. Overview of steps**

It may be helpful for manufacturers to include an overview of the steps to be performed. These steps might include reading the instructions, checking contents, collecting sample, running the test, reading the results, preparing the sample for shipping if the result is uncertain or preliminary, and calling the 800 number using the private ID number.

**7. Sample collection and handling instructions**

a. Provide instructions for collection and handling of the urine sample. It may be helpful for instructions to be phrased in question and answer format (e.g., "When should I test the urine?" or "How much sample do I need?"). The labeling should also include instructions for maintaining integrity of the sample for shipping (e.g., "cap the vial tightly," "avoid high temperatures and sunlight," "do not freeze the sample," "mail the sample immediately").

b. Manufacturers may wish to alert OTC users to possible sources of adulteration of samples or provide recommendations for minimizing tampering.

**8. Directions for performing the test**

Include step-by-step instructions for collecting and applying the sample. FDA encourages the use of illustrations. If the manufacturer chooses to describe the function of the control line in the labeling, it should be described so users do not mistake this line for a mechanism that ensures correct test results. (For example: "The control line is a check to see if enough liquid has been added. If the control line fails, the user should contact customer assistance before continuing with the test.")

The directions should clearly specify the length of time after the application of the sample, during which the test can be read or interpreted.

**9. Reading and understanding test results**

The package insert should include general instructions and diagrams explaining how to read the results and the next steps to be taken. All possible results should be described and illustrated. Include the toll-free number that OTC users can call for help with performing, reading or understanding the test. The following are suggestions for describing results:

***"Uncertain" or "Preliminary" Result*** Clarify that an uncertain result means that something in the urine has reacted with the test and the sample should be sent to the laboratory for further testing to find out if there may be drugs in the sample. Explain in OTC terms why it is important to send the sample for further testing, e.g., "It is important to understand that sometimes the test strip shows an uncertain result even when drugs have not been taken. Laboratory testing is the only way to know for sure if drugs of abuse are present in the sample."

***Negative Result*** Explain that if the test is negative, the person probably has not taken the drug(s) being tested for in the past few days. Cases for which rescreening may be desired should be clarified in the labeling, e.g., "If you still suspect drug abuse, you may want to run the test again at another time, or talk with your doctor. This is because sometimes a person can use drugs but not have drugs found in their urine. This can occur if just a small amount of drug was used, if the sample was collected too soon or too late after drug use, or if the person drank a large quantity of liquids within a few hours before giving the sample." Include an explanation that only the drugs listed will be detected by this test.

***"Invalid" or "Error" Result*** Describe what OTC users should do if the control or check line did not appear, e.g., "this means the test did not work, repeat using a new test or call the manufacturer."

**10. Clearance rates**

FDA recommends that manufacturers include information on how long it takes for a drug to leave the body. This is the drug's ***clearance rate***. The clearance rate determines how soon a person will have a positive test after taking a drug. The clearance rate also determines how long a person will continue to test positive after the last time he or she took the drug. The clearance rate for drug(s) being tested should be provided and explained at a $7^{th}$ grade level in the labeling. Table 2 can be used as a guide. You may include the clearance rate section near the specimen collection and handling instructions.

**Table 2. Suggested Guide to When You Observe a Positive Drug Test.**

| Drug | How soon after drug use? | For how long after the last drug use? |
|---|---|---|
| Marijuana/Pot (Cannabinoids) | 1 to 3 hours | 1 to 7 days |
| Crack (Cocaine) | 2 to 6 hours | 48 to 72 hours |
| Heroin (Opiates) | 2 to 6 hours | 24 to 72 hours |
| Speed/Uppers (Amphetamine/methamphetamine) | 4 to 6 hours | 48 to 72 hours |
| Angel Dust/PCP (Phencyclidine) | 4 to 6 hours | 7 to 14 days |

**11. Description of confirmation testing**

In order to fully ensure that OTC users understand the purpose of laboratory confirmation testing, you should clearly describe the meaning and purpose of this testing. Include the information that these tests are more accurate and reliable than the screening test and that they will tell if the urine is positive or negative for the drug tested.

**12. Instructions for shipping the sample**

Describe in detail the steps the OTC user will take to ship the sample, in case of an "uncertain" result.

**13. Instructions for getting laboratory results**

Include the toll-free telephone number with days and times of business and instructions concerning any materials the consumer will need to have on hand when calling (e.g., ID number). Specify how long the test result will remain on file.

**14. Referrals**

FDA encourages manufacturers of OTC screening tests to provide professional counseling and referral services though an 800 number, e.g., "Call our toll free number, 1-800-_____, between 8:00 a.m. and 8:00 p.m. Eastern Standard Time, to discuss the results of your test and what they mean."

**15. Instructions on how to obtain professional counseling**

The package insert should include advice that the individual's physician can be contacted for options for identifying and/or treating substance use or abuse problems. Include a statement that information on talking to children about drug use and abuse can be obtained from the National Clearinghouse for Drug and Alcohol Information, 1-800-729-4889.

**16. Limitations**

a. Provide an explanation of the limitations of the test, including a list of substances known to interfere. This section of the labeling could be written in a question and answer format, e.g., "What if I am taking an over-the-counter drug?" or "Could I have eaten something that could cause a false result?"

b. Provide information on why confirmation testing is needed (for example: false positives, testing errors, foods, prescription drugs).

**17. Further information**

Manufacturers may choose to provide additional useful information to the OTC user. Such information could include issues such as the prevalence of drug use, the effects of various drugs, additional telephone numbers of counseling centers, a glossary of terms relating to drug abuse, further discussion of false positive and false negative results, and laboratory confirmation. It may be helpful to word this section in a question and answer format.

**18. Additional information required by 21 CFR 809.10**

The labeling regulations for all IVD devices (21 CFR 809.10) require that you include the name and place of business of the manufacturer, packer, or distributor and the date of last (labeling) revision in the package insert.

**19. Outside box labeling**

Positive results are reported as **"uncertain," "preliminary," "inconclusive,"** or **"maybe."** The outside box labeling should reflect this. You should include this statement or a similar one on the outside box labeling:

> **(This device) is only the first-step in a two-step process for determining the presence of drugs of abuse. You should consult your health care provider or refer all "uncertain" results to the laboratory in order to complete step-two: a confirmed result (see package insert).**

**20. Other labeling**

A complete set of labeling should be provided in the 510(k), including all box labels, the package insert, and the labels or labeling on the device itself.

**Applying this guidance document to Workplace, Insurance, and Sports Testing For Drugs Of Abuse and OTC Alcohol Tests**

FDA believes that there should be consistency in its regulation of drugs of abuse screening tests used in the home, workplace, insurance, and sports settings. Concerns related to OTC use are similar in all of these settings, including concerns about sample integrity and test accuracy. As stated earlier, FDA intends to apply this guidance document to OTC tests for drugs of abuse in these non-professional use settings: home, workplace, insurance, and sports. We are also considering applying this guidance document to alcohol tests for these non-professional use settings. Comments are welcome.

FDA would continue to defer oversight for forensics (law enforcement) applications to the existing system of legal controls and would continue to defer oversight of tests for alcohol used in Department of Transportation programs to the existing oversight of the Department of Transportation and it program for conformance testing of devices. Comments are welcome.

FDA is also requesting comments on the following issues.

1. FDA seeks input on whether OTC tests using novel matrices should include pharmacodynamic information and how this can be simplified to be useful to OTC users.

2. FDA seeks input on whether screening of potential employees versus incidence testing of employees in workplace settings would warrant submitting different kinds of premarket studies or different labeling.

3. FDA seeks input on what types of controls, if any, should be applied to potential false negative results in workplace, insurance, and/or sports settings.

4. FDA seeks input on what testing, if any, should be used for confirming presumptive positives in screening tests for alcohol.

5. FDA recognizes the importance of the authority of the Substance Abuse and Mental Health

6. Administration (SAMHSA) in regulating federal workplace testing. To clarify this role, labeling for products for workplace testing could contain the statement below:

   **"It is the responsibility of those organizations required to follow Department of Transportation (DOT) or the Substance Abuse and Mental Health Administration (SAMHSA) Workplace Drug Testing Guidelines to determine that use of this product satisfies the criteria for workplace testing established under DOT and SAMHSA."**

   Is this language appropriate? Are there other methods for communicating this information?